

EXHIBIT 8

IN THE UNITED STATES
PATENT AND TRADE MARK OFFICE

DECLARATION OF TOMAS D. DIVINAGRACIA
RE PATENT APPLICATION NO. 09/364,343

I, Tomas D. Divinagracia, of Quincy, MA, do declare and say as follows:

1. My professional background is as follows: I graduated from the University of St. Thomas in Manila, Philippines. I am a Doctor of Medicine (MD) and General Surgeon at Quincy Medical Center, Quincy, MA, and have a private practice. I have been a practicing physician for 30 years.

As such, I am deeply familiar with means of treating wounds in patients, including wound irrigation delivery systems using separate sealed sterilized bottles of saline solution, sterile bowls and sterile syringes, which are presently in use.

2. I have reviewed U.S. patent application No. 09/364,343 entitled "Wound Irrigation and Debriding System", invented by Jacqueline R. Doyle and Kenneth F. Short, and I am familiar with this invention.
3. I have reviewed the U.S. Patent Office Action dated 02/07/02 and the cited references: U.S. Patents No. 4,752,288 of Hussey, entitled "Disposable Enema Unit"; No. 2,135,052 of Rose, entitled "Nasal Douche"; and No. 4,894,054 of Reddick, entitled "Douche Apparatus"; and No. 6,066,325 of Wallace et al, entitled "Fragmented Polymeric Composition and Methods for their use".
4. In my opinion, the wound irrigation and debriding system of Jacqueline Doyle and Kenneth Short is a significant and surprising advance in this field of medicine as compared with the present state of the art. The accepted system of using independently packaged items which are then reassembled and in which the

solution is drawn-into a syringe and injected into the patient is time-consuming, especially in emergencies, subject to possible contamination, and requires discard into a Sharps Hazard Container.

5. The enema unit of Hussey is used in an entirely different medical procedure than the wound irrigation and debriding system of the inventors. The enema must be inserted into the rectum of the patient; the wound irrigation and debriding system of the inventors in the pending application is non-invasive, and is not capable of acting as an enema. Nor, in my opinion, is the enema of Hussey capable of performing the wound irrigation and debriding claimed by the present inventors.

Structurally, Hussey's enema and applicants' wound irrigation system are substantially different. Because Hussey claims an enema, it requires a rectal tip and lubricant for insertion into the rectum. It also requires a heat-shrunk protective sleeve fixed to a ball and the rectal tip.

6. As a practicing physician knowledgeable in the field of wound irrigation, enemas and douches, it would not be obvious to me to combine the enema of Hussey with any of the prior art patents cited by the examiner as listed in paragraph 3 of this Declaration in order to produce applicants' invention.
7. If Hussey, as I conclude, is designed as an enema, and is not meant or capable to be a wound irrigation and debriding system as taught by applicants, the filter used by Reddick's douche apparatus would not change the nature of Hussey's invention and would certainly not make applicants' invention obvious to me or anyone else skilled in the art of this invention.
8. My conclusions are the same in this regard as concerns the angled nozzle used by Rose's nasal douche, and the hydrogels of Wallace, et al.
9. I do not conclude that applicants' invention lies in the use of filters, types of nozzles or the ability to dispense fluids.

10. My understanding of applicants' wound irrigation and debriding system is that, for the first time known to me, this invention provides a one-piece system (as opposed to present independently packaged units), which does not require a syringe, nor Sharps Hazards disposal procedures, is non-invasive, and which is more efficient, quicker, safer, and less expensive than presently available today.

Witness my hand and seal this 11th day of DEC. 2002.

Thomas D. Divinagracia

Witness: Mayanne Gosselin

Thomas D. Divinagracia
Signature